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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,954	02/19/2002	Matthias Durst	SCHU-204.1	2787

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,954	DURST ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed January 6, 2006 in response to the Office Action of September 9, 2005, is acknowledged and has been entered. Previously pending claims 51 and 52 have been amended. Claims 51-57 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections

3. Claim 51 is objected to for containing subject material that is drawn to a non-elected invention. Appropriate correction is required.

New Rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 52-54 are rejected under 35 U.S.C. 101 because the claimed invention, an antibody, is directed to non-statutory subject matter.

The claims read on an antibody that is found in nature. Products of nature do not constitute patentable subject matter as defined in 35 USC 101. See MPEP 2105. Since

an antibody does not exist in nature in purified form, it is suggested that Applicant use the language "isolated" or "purified" in connection with the antibody to identify a product that is found in nature.

Rejections Maintained

Claim Rejections - 35 USC § 112

5. Claim 51 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants amended claim 51 to clearly define the first agent as an antibody which specifically binds to an amino acid sequence encoded by SEQ ID NO:1 or 2, however, Applicant still fails to clarify the "other agent" which binds to the first agent.

6. Applicants argue that the second agent of claim 51 is clearly defined as one which binds the first agent and states that original claim 8 defines the agents (point iii of remarks).

This argument has been considered but has not been found persuasive because the term **"agent"** is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification does not define the term agent nor does it give a limiting example of what an agent may consist of. Original claim 8 recites "An antibody directed against the polypeptide according to

claim 4 or 5" and does not define the second, "other agent". Given the above reasons, the metes and bounds of the claims cannot be determined. Amending claim 51, for example, to include the limitations of claim 57 may obviate the rejection.

7. Claims 51 and 57 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody and a kit comprising an antibody that specifically binds to **the** amino acid sequence encoded by SEQ ID NOs:1 or 2, does not reasonably provide enablement for a kit comprising an antibody that specifically binds to **an** amino acid sequence encoded by SEQ ID NOs:1 or 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants amended claim 51 to recite "wherein said polypeptide comprises **an** amino acid sequence encoded by SEQ ID NO:1 or SEQ ID NO:2" to help define the polypeptide to which the antibody specifically binds. However, the claim is now broadly drawn to an antibody that specifically binds to **any** polypeptide encoded by **an** amino acid sequence of SEQ ID NO:1 or 2. It cannot be predicted which of the broadly claimed antibodies of the kit that binds to **any** polypeptide encoded by an amino acid sequence of SEQ DI NO:1 or 2 would function as claimed and contemplated.

8. Applicants argue that the amendments to claims 51 and 52 renders the rejection moot. The amendment of claim 52, does, in fact, define the sequence to which the

antibody binds, however, the amendment of claim 51 still reads broadly on any polypeptide sequence encoded by SEQ ID NO:1 or 2, of which any antibody that specifically binds to any of the polypeptides encoded by SEQ ID NO:1 or 2 would not predictably function as claimed and contemplated for the reasons set forth above. As stated in the previous Office Action, page 9, the specification only discloses SEQ ID NO:1 and 2 as encoding the polypeptides characteristic of early or late passages of HPV immortalized cells. Antibodies that specifically bind these two defined polypeptides are enabled. Amendment of claim 51 to recite, for example, "wherein said polypeptide comprises **the** amino acid sequence encoded by SEQ ID NO:1 or SEQ ID NO:2", may obviate the rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 52-56 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,020,478, Hillman et al, filed 2/28/1997 (see sequence search result #3, issued patents).

The claims are drawn to an antibody which specifically binds to a polypeptide characteristic of early or late passage HPV of immortalized cells, said polypeptide comprises the amino acid sequence encoded by SEQ ID NO: 1 or 2 (claim 52), wherein said antibody is polyclonal (claim 53), wherein said antibody is monoclonal (claim 54), a fragment of the antibody (claim 55), and wherein said fragment is a Fab fragment (claim 56).

US Patent 6,020,478 teaches the production of polyclonal and monoclonal antibodies that bind to SEQ ID NO:1, an amino acid sequence that is 97.9% homologous to the amino acid sequence SEQ ID NO:1 of the instant Application (see sequence search result #3, issued patents) and antibody fragments including Fab fragments (col. 2, lines 23-25; col. 16, lines 58-64; col. 17, lines 20-60). It would be expected that a subset of polyclonal and monoclonal antibodies produced against SEQ ID NO:1 taught by US Patent 6,020,478 would specifically bind to a polypeptide characteristic of early or late passage HPV of immortalized cells, said polypeptide comprises the amino acid sequence encoded by SEQ ID NO: 1.

Claim Rejections - 35 USC § 103

10. Claims 51 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,020,478 in view of Stratagene catalog, 1988.

It is noted that the preamble recitation of a kit "useful for diagnosis of cervical lesions and the evaluation of the potential progression potential of cervical lesions" is

merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredients *per se*, which is an antibody and agent or a kit comprising an antibody and agent that detects a polypeptide.

The claims are drawn to a kit comprising an antibody which determines the presence or absence and/or level of a polypeptide characteristic of early or late passages of HPV immortalized cells, wherein said polypeptide comprises an amino acid sequence encoded by SEQ ID NO:1 or 2, wherein the antibody specifically binds to said polypeptide, and another agent which binds to said antibody (claim 51), wherein the agent detects said antibody (claim 57).

US Patent 6,020,478 teaches polyclonal antibodies that bind to SEQ ID NO:1, an amino acid sequence that is 97.9% homologous to the amino acid sequence SEQ ID NO:1 of the instant Application (see sequence search result #3, issued patents) and antibody fragments including Fab fragments (col. 2, lines 23-25; col. 16, lines 58-64). It would be expected that a subset of polyclonal antibodies produced against SEQ ID NO:1 taught by US Patent 6,020,478 would specifically bind to a polypeptide characteristic of early or late passage HPV of immortalized cells, said polypeptide comprises the amino acid sequence encoded by SEQ ID NO: 1 or 2. US Patent 6,020,478 teaches the detection of the polypeptide using antibodies and a label for the detection of the antibodies. US Patent 6,020,478 teaches that the antibodies may be labeled by joining them with a reporter molecule (col. 22, lines 5-34). US Patent 6,020,478 does not teach a kit comprising the antibody and agent.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the antibody and labeling agent taught by US Patent 6,020,478 into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

11. All other rejections recited in the Office Action mailed September 9, 2005 are hereby withdrawn.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER